

# UNITED STATES PATENT AND TRADEMARK OFFICE



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| PPLICATION NO.   | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--|--------------------|----------------------|-------------------------|-----------------|
| 09/491,596   | 01/25/2000         | Todd Elliott Piper   | 1199                    | 8751            |
| 27310 7:   | 590 12/19 2001     |                      |                         |                 |
| PIONEER HI-BRED INTERNATIONAL INC.<br>7100 N.W. 62ND AVENUE<br>P.O. BOX 1000 |                    |                      | EXAMINER                |                 |
|  |                    |                      | MEHTA, ASHWIN D         |                 |
|  | JOHNSTON, IA 50131 |                      | ART UNIT                | PAPER NUMBER    |
|  |                    |                      | 1638                    |                 |
|  |                    |                      | DATE MAILED: 12/19/2001 | L               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| -1-   |  | Application No.   | Applicant(s)   |  |  |  |
|---|--|---|--|--|--|--|
|   | •  | 09/491,596  | PIPER TOSCILLIBITE   |  |  |  |
|   | Office Action Summary  | Examiner  | Art Unit   |  |  |  |
|   |  | Ashwin Mehta  | 1638   |  |  |  |
|   | The MAILING DATE of this communication a   | ppears on the cover sheet w   | ith the correspondence address   |  |  |  |
| Period fo   | · ·  |   |  |  |  |  |
| THE N - Exter after - If the - If NO - Failui - Any r   | ORTENED STATUTORY PERIOD FOR REF MAILING DATE OF THIS COMMUNICATION issons of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication period for reply specified above is less than thirty (30) days a riperiod for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will by state eply received by the Office later than three months after the maid patent term adjustment. See 37 CFR 1 704(b) | No. 136 at Thinble lent nowever may a epiy within the statutory minimum of that bod will apply and will expire SIX (6) MON tute cause the application to become A | repr. betime: TR:  ty buildays in the consideration is  NTHS from the maining data. It mis until build BANDONED 135 U.S.C. § 137 |  |  |  |
| 1)  | Responsive to communication(s) filed on  |   |  |  |  |  |
| 2a)[X]  |  | This action is non-final.   |  |  |  |  |
| 3)  | Since this application is in condition for allo  |   | tters, prosecution as to the ments is  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle. 1935 C.D. 11, 453 O.G. 213  |  |   |  |  |  |  |
| Dispositi   | on of Claims   |   |  |  |  |  |
| 4) Claim(s) 1-51 is/are pending in the application.   |  |   |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |   |  |  |  |  |
| 5)  | 5) Claim(s) is/are allowed.  |   |  |  |  |  |
| 6)[]  | 6)[☑ Claim(s) <u>1-51</u> is/are rejected.   |   |  |  |  |  |
| 7)  | Claim(s) is/are objected to.   |   |  |  |  |  |
| 8)  | Claim(s) are subject to restriction and  | d/or election requirement.  |  |  |  |  |
| Applicati   | on Papers  |   |  |  |  |  |
| 9) The specification is objected to by the Examiner   |  |   |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner   |  |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1 85(a)  |  |   |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner   |  |   |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |   |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |  |   |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |   |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f)  |  |   |  |  |  |  |
| a)  | ☐ All b)☐ Some * c)☐ None of:  |   |  |  |  |  |
|   | 1. Certified copies of the priority docume   |   |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17 2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |   |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U S C § 119(e) (to a provisional application   |  |   |  |  |  |  |
| a) The translation of the foreign language provisional application has been received 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121  |  |   |  |  |  |  |
| Attachmer   | at(s)  |   |  |  |  |  |
| 2) Notic  | ce of References Cited (PTO-892)<br>ce of Draftsperson's Patent Drawing Review (PTO-948)<br>mation Disclosure Statement(s) (PTO-1449) Paper No(  | 5) Notice of  | Summary: PTO-413- Pager No. 3<br>Informal Patent Application: PTC: 15.   |  |  |  |
| S Patent and 1  | rademark Office  |   |  |  |  |  |

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#### DETAILED ACTION

The text of those sections of Title 35, U.S. Code, not found in this action can be found in a prior action.

## Claim Objections and Rejections

- 1. Claims 1, 21, 37, and 40 remain objected to for the inclusion of a blank line where the ATCC accession number should be. Applicant's intent, indicated in the paper submitted 03 October 2001, that a deposit will be made with the ATCC and the claims amended to recite the accession number upon notice of allowable claims (page 5, second paragraph), is acknowledged.
- 2. Claims 1, 2, 3(amended) 4, 5-6 (both amended), 7, 8 (amended), 9-13, 14-16 (all amended), 17, 21, 22 (amended), 23, 24-25 (both amended), 26, 27 (amended), 28-32, 33-35 (all amended), 36-40, 41 (amended), 42, 43 (amended), 44, and 45-46 (both amended) remain and new claims 50 and 51 are rejected under the judicially created doctrine of obviousness-type double patenting, for the reasons of record stated in the last Office action on page 3, under item 3 for claims 1-17 and 21-46.
- 3. Claims 4, 5 (amended), 23, and 24 (amended) remain and claims 6 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the last Office action on page 4 under item 5.

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- Claims 1, 2, 3 (amended) 4, 5-6 (both amended), 7, 8 (amended), 9-13, 14-16 (all amended), 17-20, 21, 22 (amended), 23, 24-25 (both amended), 26, 27 (amended), 28-32, 33-35 (all amended), 36-40, 41 (amended), 42, 43 (amended), 44, and 45-46 (both amended), 47-49 remain and new claims 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the last Office action on page 5 under item 6 for claims 1-49.
- 5. Claims 17, 36, and 43 (amended) remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the last Office action on page 8 under item 12.
- 6. Claims 1, 2, 3(amended) 4, 5-6 (both amended), 7, 8 (amended), 9-13, 14-16 (all amended), 17-20, 21, 22 (amended), 23, 24-25 (both amended), 26, 27 (amended), 28-32, 33-35 (all amended), 36-40, 41 (amended), 42, 43 (amended), 44, and 45-46 (both amended), 47-49 remain and new claims 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the last Office action on page 9 under item 14 for claims 1-49.

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- Claims 1, 2, 3(amended) 4, 5-6 (both amended), 7, 8 (amended), 9-13, 14-16 (all amended, 17, 21, 22 (amended), 23, 24-25 (both amended), 26, 27 (amended), 28-32, 33-35 (all amended), 36-40, 41 (amended), 42, 43 (amended), 44, and 45-46 (both amended) remain and new claims 50 and 51 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carrigan et al. (U.S. Patent No. 5,936,148), for the reasons of record stated in the last Office action on page 11 under item 15 for claims 1-17 and 21-46.
- 8. New claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "seed further comprises genetic or cytoplasmic male sterility" renders the claim indefinite. Plants can display male sterility, not seed. Insertion of --factors-- after "sterility" would obviate this rejection.

### Response to Arguments

9. Applicant's arguments filed 03 October 2001 have been fully considered but they were not found persuasive.

### **Double Patenting**

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Applicants traverse the rejection to claims 1-17 and 21-46 under the judicially created doctrine of obviousness-type double patenting. Applicants submit that the claimed plant, PH54H, cannot be rendered obvious or lacking novelty as it possesses a unique combination of traits, which confers a unique combination of genetics. Applicants go on to list several differences between PH54H and that claimed in U.S. Patent No. 6.096,953, PH1GC (response, paragraph bridging pages 5-6 to the table bridging pages 6 and 7).

Applicant's arguments were fully considered as they apply to claims 1, 2, 3(amended) 4, 5-6 (both amended), 7, 8 (amended), 9-13, 14-16 (all amended, 17, 21, 22 (amended), 23, 24-25 (both amended), 26, 27 (amended), 28-32, 33-35 (all amended), 36-40, 41 (amended), 42, 43 (amended), 44, and 45-46 (both amended) and new claims 50 and 51, but were not found persuasive. Though Applicants contend that PH54H has a unique combination of genetics, information concerning the genes of the cultivar is not provided. Further, "PH54H" is an arbitrarily assigned designation, which does not itself distinguish it from other plants. Insertion of the ATCC accession number into the claims will overcome the rejection.

#### 35 USC § 112

Applicants traverse the rejection to claims 4, 5, 23, and 24 under 35 U.S.C. 112, second paragraph. Applicants argue that the claims are directed to tissue culture of regenerable cells derived from the plant of claims 2 and 21, which are defined in the specification. Applicants argue that one of ordinary skill in the art will clearly understand what is meant by tissue culture, and the deposit of PH54H adds a high degree of clarity and precision to the claim (response, page 8, paragraphs 1 and 2).

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Tissue culture introduces many chromosomal changes to plant cells. It is unclear what the characteristics of the claimed tissue culture are, since the characteristics of the PH54H-derived cells would be affected by the chromosomal changes. With regard to amended claims 6 and 25, it is unclear what the characteristics of the plant regenerated from tissue culture would be, given that tissue culture can introduce many chromosomal changes in the plant cells, resulting in regeneration of plants with undetermined characteristics. It is again suggested that claims 4 and 23 be amended to indicate that the tissue culture regenerates plants having all of the physiological and morphological characteristics of maize inbred line PH54H. It is further suggested that the recitation that was deleted from claims 6 and 25 be reinserted.

- Applicants traverse the rejection to claims 1-49 under 35 U.S.C. 112, second paragraph.

  Applicants again indicate that the deposit will be made and claims amended upon notice of allowability (response, paragraph bridging pages 8 and 9). As the application is not in condition for allowance, the rejection is maintained.
- Applicants traverse the rejection to claims 17, 36, and 43 under 35 U.S.C. 112, second paragraph. Applicants argue that the claims clearly state that somewhere in the breeding process, regardless of the breeding techniques used, inbred line PH54H must be used. Applicants argue that for claims 17 and 36, that the number of generations the claimed plant resides from the starting material is not a factor, as long as the end product was developed by use of the invention. Applicants argue that the claims are definite because only plants derived through the use of PH54H are within the scope of the claims (response, page 12, second and third full paragraphs).

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However, PH54H is not the only plant that is used to make the claimed plants.

Therefore, with each generation, any number of traits displayed by PH54H may be eliminated. It is also unknown what traits would be introduced by the other plants used in the breeding methods, especially since the characteristics of the other plants are unknown. The plants are not defined as the traits that the claimed plants possess are not defined.

Applicants traverse the rejection of claims 1-49 under 35 U.S.C. 112, first paragraph. Applicants indicate that the actual ATCC deposit will be delayed until receipt of notice that the application is otherwise allowable (response, page 13, first paragraph). Applicant's intent is acknowledged. As the application is not otherwise in condition for allowance, the rejection is maintained for claims 1-49, and applied to new claims 50 and 51.

#### 35 USC § 102 & 103

15. Applicants traverse the rejection to clams 1-17 and 21-46 under 35 U.S.C. 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious under Carrigan et al. Applicants again argue that PH54H and the cultivar taught by Carrigan et al., PH1GC, differ, and go on to list several examples of the differences (response, page 14, second full paragraph to page 15, second full paragraph). Concerning claims 1-13, 15-32, 34-40, 42-44, and 47-49: Applicants indicate that the deposit will be made and claims will be amended with the ATCC accession number upon indication of allowable subject matter (page 16, first full paragraph). Regarding claims 14, 33, 41, 45, and 46: Applicants argue that though PH1GC and PH54H exhibit similar cold test scores and exhibit similar root lodging resistance, what is being claimed

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is not the trait but the unique combination of alleles contained in PH54H, and that it is this unique combination of genetics and traits in PH54H that will give rise to the claimed plants resulting from breeding with this material (page 14, third full paragraph). Applicants argue that each PH54H-derived plant has an additional benefit unique to each specific cross using PH54H as one of its ancestors, and thus deserve to be considered new and nonobvious compositions in their own right as products of crossing when PH54H is used as a starting material (page 16, fourth full paragraph).

Regarding claims 1-5, 7-13, 15-17, 21-24, 26-32, 34-40, 42-44, 47-49, and new claims 50 and 51: Applicant's intent to deposit seed and amend the claims is acknowledged. The rejection is maintained, as all of the claims are not yet in condition for allowance. Regarding Applicants' traverse of claims 14, 33, 41, 45, and 46: The claims do not make any mention of the alleles or "genetics" of cultivar PH54H. The claims indicate that the plants need to have two of the indicated traits of PH54H, not the genes of PH54H that produce those traits. Further, the traits listed in the claims are not unique to PH54H. Other plants may possess any one or more than one of these traits. The claims do not indicate what feature of any of these traits makes it unique only to PH54H. Further, the claims do not distinguish plants that possess at least two of the listed traits that do not have PH54H in its ancestry, from those that do. As other plants have the listed traits, the claimed plants can be produced without PH54H. Regarding newly amended claims 6 and 25, the claims now read on somaclonal variants that do not retain PH54H-derived genetic material, as stated above. The process of making the claimed plants does not distinguish the plants themselves from those taught by the reference. See In re Thorpe, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over

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prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. As discussed in the last Office action, Carrigan et al. does teach a plant having at least two of the indicated traits.

- 16. No claim is allowed.
- Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

# **Contact Information**

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone

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are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at 703-308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A.M. December 14, 2001

DAVID T. FOX PRIMARY EXAMINER

PRIMARY EXAMINED
GROUP 180 (Ce 38)